REMARKS

I. Support for the Amendments to the Claims

Claims 1-35 and 66 are currently in the application. Claims 1, 35, and 66 have been amended. The amendments to claims 1, 35, and 66 are made without prejudice to pursuit of the previous claims in an appropriate continuation application.

Support for the amendments to claims 1, 35, and 66 can be found throughout the specification and claims as originally filed. No new matter has been added by the amendments to the claims.

Additional support for the amendments to claims 1, 35, and 66 can be found in the language of original claims 1, 35, and 66, respectively, and in the specification, e.g., from page 16, line 1, to page 18, line 3; from page 28, line 33, to page 30, line 8; and in the Examples.

II. Status of the Claims

Claims 1-35 and 66 are currently in the application. Claims 1, 35, and 66 have been amended. The amendments to claims 1, 35, and 66 are made without prejudice to pursuit of the previous claims in an appropriate continuation application.

III. The Form PTO-892 and the Information Disclosure Statements

Applicants thank the Examiner for providing the previously cited PTO-892.

Applicants thank the Examiner for acknowledging the Information Disclosure Statements of March 31, 2005, and August 8, 2006.

IV. The Withdrawal of the Rejection of Claims 3, 11, 21, and 23-24 under 35 U.S.C. §112, Second Paragraph

Applicants thank the Examiner for withdrawing the previous rejection of claims 3, 11, 21, and 23-24 under 35 U.S.C. §112, second paragraph, for alleged indefiniteness.

V. The Withdrawal of the Rejection of Claim 13 under 35 U.S.C. §103(a) over Mitchell in view of Burgoyne

Applicants thank the Examiner for withdrawing the previous rejection of claim 13 under 35 U.S.C. 103(a) as allegedly unpatentable over Mitchell (WO 00/21973; issued April 20, 2000) in view of Burgoyne (U.S. Patent 5,496,562; issued March 5, 1996).

VI. The Rejection of Claims 1-12, 14-35, and 66 under 35 U.S.C. §103(a) over Mitchell in view of Burgoyne is Traversed, but Accommodated in Part

The Examiner has maintained the rejection of claims 1-12, 14-35, and 66 under 35 U.S.C. 103(a) as unpatentable over Mitchell (WO 00/21973; issued April 20, 2000) in view of Burgoyne (U.S. Patent 5,496,562; issued March 5, 1996). Applicants again traverse the rejection and respectfully request reconsideration of these claims.

The Patent Office alleges:

Mitchell et al. disclose the method steps (a)-(e) as recited in instant claim 1 (See pg. 2, third paragraph) and the method steps as recited in claim 4 (See pg. 2, third paragraph). The nucleic aid is retained by the filter substantially in the absence of ionic interaction (See column 2, last paragraph), and by physically retarding the movement of the nucleic acid down the filter (See pg. 3, first paragraph). The nucleic acid is heated to an elevated temperature, whilst retained by the filter prior to elution and the temperature is about 90°C, (See pg. 3, second paragraph, pg. 6, first paragraph, pg. 12, first paragraph and pg. 25, experiment 6). There is a solution for rupturing intact whole cells to leave condensed nuclear material and a lysis solution for lysing nuclear material (See pg. 3, third paragraph). The sample comprises whole blood, which has been treated with a red blood cell lysis solution, whilst the white cells containing the nucleic acid are retained by the filter as a retentate (See pg. 6, third paragraph). A filter material is selected which provides no barrier to cells, but enables the cells to be retained by the filter as a retentate (See pg. 6, second paragraph). The pore size of the filter is 4.5um (See pg. 11, tablel). The filter used in the method comprises a plurality of fibers and has a substantially disordered structure, the fiber diameters are selected from the range of l um to 10 um (See pg. 9, fourth paragraph). The fiber is glass fiber, silica based or plastic based fiber (See pg. 10,first paragraph). It is possible to isolate nucleic acid in the absence of a chaotrope (See pg. 10, second paragraph). Genomic DNA is a desired target or nucleic acid is RNA (See pg. 15, fourth paragraph).

Mitchell et al. do not disclose the method steps (f)-(g) as recited in instant claim 1.

Burgoyne discloses that the blood-stained paper was dried, and sent through the ordinary mail so that it spent at least three days in the mail, and had the DNA extracted from it (See column 4, lines 4 1-45). A card loaded with a DNA sample is air dried at room temperature (See column 5, lines 43-44).

One of ordinary skill in the art would have been motivated to apply the method steps of drying the solid phase medium with the cell lysate comprising nucleic acid and storing the dried solid phase medium with the nucleic acid because it would have been useful for long time storage, such as 36 months (See column 4, lines 21-25) or four years (See column 5, lines 1-4). It would have been prima facie obvious to apply the method steps (f)-(g) as recited in instant claim 1. [Pp. 2-3.]

Applicants respectfully disagree. Essentially, the Patent Office alleges that Mitchell discloses steps (a)-(e), but not (f)-(g) (i.e., drying and storing the nucleic acid on the solid phase medium). The Patent Office alleges that Burgoyne discloses drying DNA samples on a card and storing them. Claims 1-34 depend, either directly or indirectly, on claim 1.

As noted previously, in the present invention, the improvement is more than the predictable use of prior art elements according to their established functions.

Mitchell uses glass or plastic for the solid phase medium (p. 10). The cells are lysed in the matrix (e.g., p. 8, pp. 14-15, etc.), and the isolated DNA is eluted (e.g., p. 11). Example 1 (see p. 18) describes a method whereby whole blood is added to the column and filtered to waste. A red blood cell lysis buffer is added (to lyse RBC's) and filtered to waste. SDS is added and filtered to waste, TE is added and filtered to waste (twice). The column is heated, additional TE is added, and the DNA in solution is captured by elution. The SDS and TE are not part of the same solution, but the current claim 1 is directed to "a solution comprising a surfactant or detergent." In Mitchell, they are added separately and filtered to waste. Finally, as the Patent Office concedes, there is no drying of the DNA on the filters and no storage.

The Patent Office alleges, however, that Burgoyne describes the drying and storage. Burgoyne uses cellulose or plastic for the solid phase medium (c. 2). The DNA can be stored, or it can be extracted or eluted (cc. 4-6). Burgoyne describes a solution of SDS, EDTA, and Tris. Burgoyne also describes a composition comprising a weak base, a chelating agent, an anionic surfactant or anionic detergent and optionally uric acid or a urate salt. Unlike the present invention, however, the card comprises the composition prior to its contact with the sample. In the present invention and in Mitchell, the solutions are added after the sample.

In Mitchell, the lysis solutions are added sequentially in order to function. Burgoyne uses a chemical composition of the base, chelator, detergent and uric/urate salt that is already deposited on the solid matrix.

Applicants respectfully submit that the previous language of independent method claims 1, 35, and 66 made it clear that the solution was added to the medium after the sample, which comprised a cellular retentate (i.e., intact whole cells retained in or on the medium).

In the present language of claim 1, the sample is added to the solid phase medium first and then the archiving agent (a solution comprising a surfactant or detergent; step d), followed by drying and storage. In claims 35 and 66, the solution simultaneously comprises a surfactant or detergent, a weak base, and a chelating agent. Therefore, the present invention is distinguishable in that one solution is added to the sample and not sequentially as in Mitchell.

The Patent Office alleges, in pertinent part:

Mitchell's buffers consist of a red cell lysis solution, a white cell lysis solution, a wash buffer, a buffer to maintain the double strandedness of the DNA and then the elution buffer used in the presence of heat. The process is for immediate DNA purification. In the present application, ***after*** the application of cellular sample to the solid support, the cells are lysed with the surfactant or detergent solution. After contact with the solution, the sample on the solid support is dried (Claim 1 f and g) and stored for up to 5 months (Claim 9) before DNA isolation. The detergent/surfactant solution of Claim 1 d is a liquid format of FTA® (see claims 17, 19, 20). In Mitchell, the buffer compositions are not able to allow the DNA to be stored on the solid support so that the DNA does not degrade; none of the chemical protectants are present in the buffers as they are in the present invention.

> The response argues that Mitchell et al. disclose that the SDS and TE are added separately and filtered to waste, e.g. in Mitchell, the lysis solutions are added sequentially in order to function. However, the limitation as recited in the instant claim is "contacting the cellular retentate with a solution comprising a surfactant or detergent". The limitation does not exclude that there is only one solution containing all the surfactants or detergents. Thus one of ordinary skill in art would have more than one chance to add more than one different solution to optimize a condition for isolating and storing nucleic acid. [P. 4.]

Applicants respectfully disagree, but have amended claims 1, 35, and 66.

Another distinction is the drying of the sample for storage and archiving of DNA. In Mitchell states (p. 7, ll. 15-20) that if the filter is allowed to dry the DNA is recoverable but

sheared and, where the method is carried out in a column, indicates the need for using a vapor block to prevent drying from occurring, because this is undesirable. Such a method is, therefore, ill-suited to archiving.

The Patent Office appears to have misunderstood this point, which was asserted in the previous action. The Patent Office alleges, in pertinent part:

> The response argues that in Mitchell the DNA dried may be sheared...drying of the filter may be avoided. However, because Mitchell does no disclose the method steps (f)-(g) as recited in instant claim 1, and there is no limitation recited in the claims that an isolated DNA is sheared, the reference of Burgoyne is applied in that Burgoyne discloses that the blood-stained paper was dried...and a card loaded with a DNA sample is air dried at room temperature...[P. 4]

In the present claims, there is **no limitation that the isolated DNA is sheared,** because **one of the advantages of the present invention is that there is drying, followed by isolation, to *avoid* shearing** (*unlike* Mitchell, in which drying is equated with shearing).

While it is true that Burgoyne discloses drying the matrix, it should be noted that Burgoyne fails to mention adding a solution to the already applied sample. Instead, the solution of Burgoyne is added to the matrix and dried prior to application of the sample.

The Patent Office alleges, in pertinent part:

> The response also argues Burgoyne uses a chemical composition of the base, chelator, detergent and uric/urate salt that is already deposited on the solid matrix. The limitation as recited in the instant claim is "drying the solid phase medium with the cell lysate comprising the nucleic acid". The limitation does not exclude that the solid phase does not have the chemical composition. [P. 4.]

Applicants respectfully disagree, noting that **the chemical composition of Burgoyne would lyse cells isolated thereon *prior* to addition of the solution**. The disclosure of

Burgoyne describes a method for lysing cells and isolating DNA on a card upon contacting the cells with the card. In addition, in the present application only heat (rather than chemical extraction [e.g., via phenol/chlorofom] is applied to the glass fiber solid support. These are two totally different means of extracting the DNA from the matrices; the phenol chloroform extraction results in double stranded DNA and the heat elution results in single stranded DNA by virtue of DNA denaturation.

In essence, the difference between Burgoyne and the present invention is that in Burgoyne, the chemical composition is deposited on the matrix and dried and then is contacted by cellular samples, whereas in the present invention, the solution is applied to the solid matrix after the matrix contains the samples.

Nothing in Mitchell would suggest to one of skill in the art that it should be combined with Burgoyne, or vice versa, to produce the present invention (single solution application and subsequent drying for archiving). In particular, one of skill in the art would not cite Mitchell's method for archiving since the method disclosed therein is for rapid preparation of DNA immediately after the addition of the sample.

Thus, there is no teaching, suggestion or motivation in Mitchell or Burgoyne that would have led on of ordinary skill in the art to combine and/or modify these teachings to arrive at the claimed invention, nor is the present invention merely a variation on known work in the field of endeavor that one of ordinary skill in the art would have been predictable to one of ordinary skill in the art, nor is it chosen from a finite number of identified, predictable solutions, with a reasonable expectation of success. In the present invention, therefore, the improvement is more than the predictable use of prior art elements according to their established functions.

Applicants traverse the rejection and respectfully submit that, even prior to amendment, claims 1, 35, and 66 (and therefore claims dependent on claim 1) were not

obvious over Mitchell in view of Burgoyne. The amendments to claims 1, 35, and 66 merely reinforce the timing of the steps as previously presented by sequential enumeration in a method claim format.

Applicants respectfully submit that claims 1-12, 14-35, and 66 fulfill the requirements of 35 U.S.C. §103(a), thereby placing these claims in condition for allowance, and request the Examiner's reconsideration accordingly.

VII. The Rejection of Claim 13 under 35 U.S.C. §103(a) over Mitchell in view of Burgoyne and Mullis is Traversed

The Examiner has maintained the rejection of claim 13 under 35 U.S.C. 103(a) as unpatentable over Mitchell (WO 00/21973; issued April 20, 2000) in view of Burgoyne (U.S. Patent 5,496,562; issued March 5, 1996) as applied to claims 1-12, 14-35, and 66 and further in view of Mullis (U.S. Patent 5,187,083; issued February 16, 1993). Applicants again traverse the rejection and respectfully request reconsideration of this claim.

The Patent Office alleges:

> The teachings of Mitchell et al. and Burgoyne et al. are set forth in section 4 above. Mitchell et al. and Burgoyne do not disclose the size of the filter pore as recited in claim 13.
>
> Mullis discloses a method for obtaining substantially purified DNA from a biological sample (See column 3, lines 21-22). The filter includes a surface that reversibly and specifically retains DNA. The pore size is from about 0.2 microns to about 0.8 microns. A preferred filter comprises a membrane filter comprised of cellulose acetate and nitrocellulose having a pore size of 0.45 microns (See column 3, lines 44-54, column 7, line 44-45, column 10, lines 16-29, column 15, lines 25).
>
> One of ordinary skill in the art would have been motivated to apply the filter of Mullis with the pore size which is from about 0.2 microns to about 0.8 microns because the filter of Mullis is used in obtaining substantially purified DNA from a biological sample (See column 3, lines 21 -22). It would have been

> prima facie obvious to apply the filter of Mullis with the pore size which is from about 0.2 microns to about 0.8 microns for isolating nucleic acid as claimed. [P. 6.]

Claim 13 is dependent on claim 1, and the discussion of the rejection of claim 1 over Mitchell in view of Burgoyne also applies here.

Again, nothing in Mitchell would suggest to one of skill in the art that it should be combined with Burgoyne, or vice versa, to produce the present invention (single solution application and subsequent drying for archiving). In particular, one of skill in the art would not cite Mitchell's method for archiving since the method disclosed therein is for rapid preparation of DNA immediately after the addition of the sample.

Thus, there is no teaching, suggestion or motivation in Mitchell or Burgoyne that would have led on of ordinary skill in the art to combine and/or modify these teachings to arrive at the claimed invention, nor is the present invention merely a variation on known work in the field of endeavor that one of ordinary skill in the art would have been predictable to one of ordinary skill in the art, nor is it chosen from a finite number of identified, predictable solutions, with a reasonable expectation of success. In the present invention, therefore, the improvement is more than the predictable use of prior art elements according to their established functions.

Applicants traverse the rejection and respectfully submit that the teachings of Mullis fail to supply the deficiencies of Mitchell or Burgoyne, either alone or in combination.

Applicants respectfully submit that claim 13 fulfills the requirements of 35 U.S.C. §103(a), thereby placing these claims in condition for allowance, and request the Examiner's reconsideration accordingly.

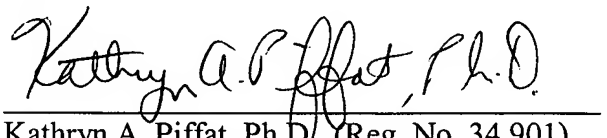
CONCLUSION

It is believed that all the claims are in condition for allowance. If discussion of any amendment or remark made herein would advance this important case to allowance, the Examiner is invited to call the undersigned as soon as convenient.

In view of the foregoing amendments and remarks, the present application is respectfully considered in condition for allowance. An early reconsideration and notice of allowance are earnestly solicited.

Applicants hereby request a three-month extension of time for the Amendment and accompanying materials. If, however, a petition for an additional extension of time is required, then the Examiner is requested to treat this as a conditional petition for an additional extension of time and the Commissioner is hereby authorized to charge our deposit account no. 04-1105 for the appropriate fee. Although it is not believed that any additional fee (in addition to the fee concurrently submitted) is required to consider this submission, the Commissioner is hereby authorized to charge our deposit account no. 04-1105 should any fee be deemed necessary.

Respectfully submitted,



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Kathryn A. Piffat, Ph.D., (Reg. No. 34,901)
EDWARDS ANGELL PALMER & DODGE, LLP
P.O. Box 55874
Boston, Massachusetts 02205
Telephone: 617-239-0100
Facsimile: 617-227-4420